

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N-0062]

PMB

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Agency Information Collection Activities; Submission for OMB Review; Comment Request; Premarket Notification for a New Dietary Ingredient

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by *[insert date 30 days after date of publication in the Federal Register]*.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Stuart Shapiro, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

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Premarket Notification for a New Dietary Ingredient—21 CFR 190.6 (OMB Control Number 0910–0330)—Extension

Section 413(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 350b(a)) provides that a manufacturer or distributor of dietary supplements or of a new dietary ingredient is to submit information to FDA (as delegate for the Secretary of Health and Human Services) upon which it has based its conclusion that a dietary supplement containing a new dietary ingredient will reasonably be expected to be safe at least 75 days before the introduction or delivery for introduction into interstate commerce of a dietary supplement that contains a new dietary ingredient. FDA's regulations at part 190, subpart B (21 CFR part 190, subpart B) implement these statutory provisions. Section 190.6(a) requires each manufacturer or distributor of a dietary supplement containing a new dietary ingredient, or of a new dietary ingredient, to submit to the Office of Nutritional Products, Labeling, and Dietary Supplements notification of the basis for their conclusion that said supplement or ingredient will reasonably be expected to be safe. Section 190.6(b) requires that the notification include: (1) The complete name and address of the manufacturer or distributor, (2) the name of the new dietary ingredient, (3) a description of the dietary supplements that contain the new dietary ingredient, and (4) the history of use or other evidence of safety establishing that the dietary ingredient will reasonably be expected to be safe.

The notification requirements described previously are designed to enable FDA to monitor the introduction into the food supply of new dietary ingredients and dietary supplements that contain new dietary ingredients, in order to protect consumers from unsafe dietary supplements. FDA uses the information collected under these regulations to help ensure that a manufacturer or distributor of a dietary supplement containing a new dietary ingredient is in full compliance with the act.

In the **Federal Register** of March 19, 2002 (67 FR 12570), the agency requested comments on the proposed collection of information. One comment was received, but it did not pertain to the information collection.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
190.6	35	1	35	20	700

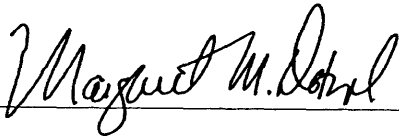
¹There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA believes that there will be minimal burden on the industry to generate data to meet the requirements of the premarket notification program because FDA is requesting only that information that the manufacturer or distributor should already have developed to satisfy itself that a dietary supplement containing a new dietary ingredient is in full compliance with the act. However, the agency estimates that extracting and summarizing the relevant information from the company's files, and presenting it in a format that will meet the requirements of section 413 of the act will require a burden of approximately 20 hours of work per submission.

This estimate is based on the annual average number of premarket notifications FDA received during the last 3 years (i.e., 1999–2001), which was 23. Twenty-three represents 12 more notifications than the agency received as an annual average during the previous 3-year period (i.e.,

1996–1998). Therefore, FDA anticipates a similar upward trend will be seen in the annual average number of notifications it receives during 2002–2004, which is estimated to be 35 ($23 + 12 = 35$).

Dated: 5-31-02
May 31, 2002.



Margaret M. Dotzel,
Associate Commissioner for Policy.

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